EXHIBIT "A"

T O R A X MEDICAL INC

URGENT: FIELD SAFETY NOTICE (REMOVAL)

LINX® Reflux Management System

(Product Codes LX-xx and LXM-xx)

[Date]

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Torax Medical, Inc ("Torax") is issuing a Field Safety Notice (removal) of certain lots of the LINX® Reflux Management System, identified below. Competent Authorities are aware of this action.

Our records indicate that you have ordered the **LINX Reflux Management System** and may have received the product lots subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR or WHO MAY USE the LINX Reflux Management System in your facility.**

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING
LINX Reflux Management System Lot Numbers.

PRODUCT NAME	PRODUCT CODE	LOT NUMBERS (Between)	DESCRIPTION / SIZE
LINX Reflux Management System	LX-xx	6100 through 14055, 14122, 14423, 15288, 15316	Implant, Clasp, 12-16 Bead, 0.7T
LINX Reflux Management System	LXM-xx		Implant, Clasp, 13-16 Bead, 1.5T

Torax has become aware of an out of specification condition which may affect a small number of devices and allow a bead component to separate from an adjacent wire link. This condition may result in a discontinuous or open LINX device.

If a device separation occurs following implantation, risk to patients may include the following:

1) Recurrence of Gastroesophageal reflux disease (GERD) symptoms
2) Need for surgical intervention to remove and/or replace the LINX Reflux Management System

The issue may not be readily detectable during the procedure by the implanting physician but may be detected by the physician or patient postoperatively. If a patient has a recurrence of GERD symptoms, physicians should consider the use of x-ray imaging to aid in determining if a device separation has occurred. **Torax does not recommend explantation of the device unless a separation has been confirmed through the use of x-ray imaging and the treating physician determines explantation to be an appropriate option for the patient.**

Even if your facility no longer has affected lots in stock, you may have patients who may warrant further diagnostic assessment (i.e. x-rays) because they previously received impacted product and now exhibit a recurrence of their GERD symptoms.

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ACTION REQUIRED: NEXT STEPS and IDENTIFICATION OF THE PRODUCT LOTS SUBJECT TO THIS RECALL:

1. Refer to Attachment 1 for assistance in identifying the product lots subject to this recall. Examine your inventory immediately to determine if you have any products subject to this recall on hand and quarantine such product(s).

2. Remove the products subject to this recall from your inventory and communicate the issue to all relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any of the devices subject to this recall have been forwarded to another facility, please contact that facility to arrange return.

3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return it to Torax Medical, Inc. within **three (3)** business days via email at brf@toraxmedical.com. **Please return the BRF even if you do not have the product lot subject to this recall.** Please feel free to contact your Torax Sales Representative if you need assistance completing the BRF.

4. Customers are required to return all unused LINX Reflux Management System subject to this recall that are in their inventory immediately. Only unused LINX Reflux Management System subject to this recall will be eligible for replacement.

5. To return unused LINX Reflux Management System subject to this recall, photocopy the completed BRF, place it in the box with the subject product(s), and do one of the following: 1) Affix the pre-paid authorized shipping label and invoice included with this notification letter and ship the devices directly to Torax Medical or 2) Contact your Distributor and coordinate shipment of affected devices to them. To help facilitate shipment of the device(s), please contact your Torax Sales Representative or contact the Quality First International at the telephone number below.

If you have additional questions regarding this Field Safety Notice, please contact Authorized Representative, Quality First International (QFI) at +44 (0) 208 221 2361.

At Torax Medical, Inc., our first priority is to support the needs of our customers and their patients, and that includes promoting the safe and effective use of our products. We recognize that this recall is disruptive to your facility and we apologize for any inconvenience it may cause.

Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

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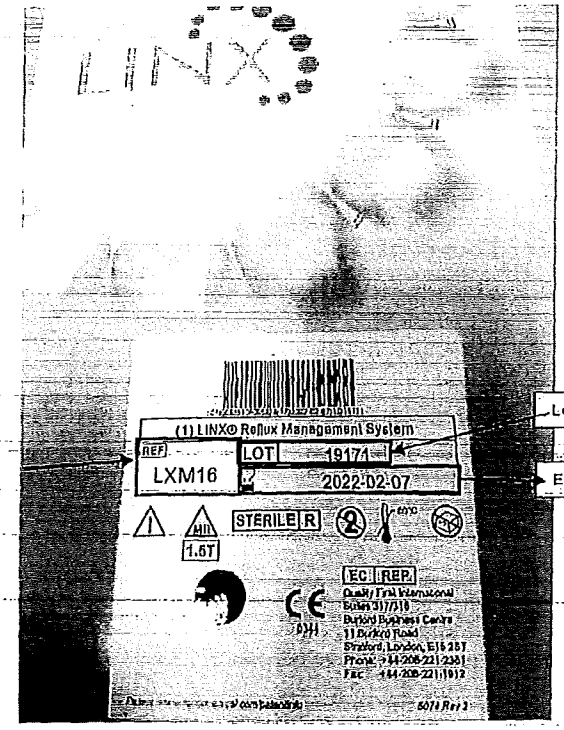
ATTACHMENT 1: Product Identification Tool for LINX Reflux Management System (See Table 1 for affected product codes and lots.)

This tool will help customers identify the product lot of LINX Reflux Management System subject to this recall. Please refer to the table above for the product expiration dates subject to this recall.

1.5T LINX® CARTON (Model Number LXM-xx)



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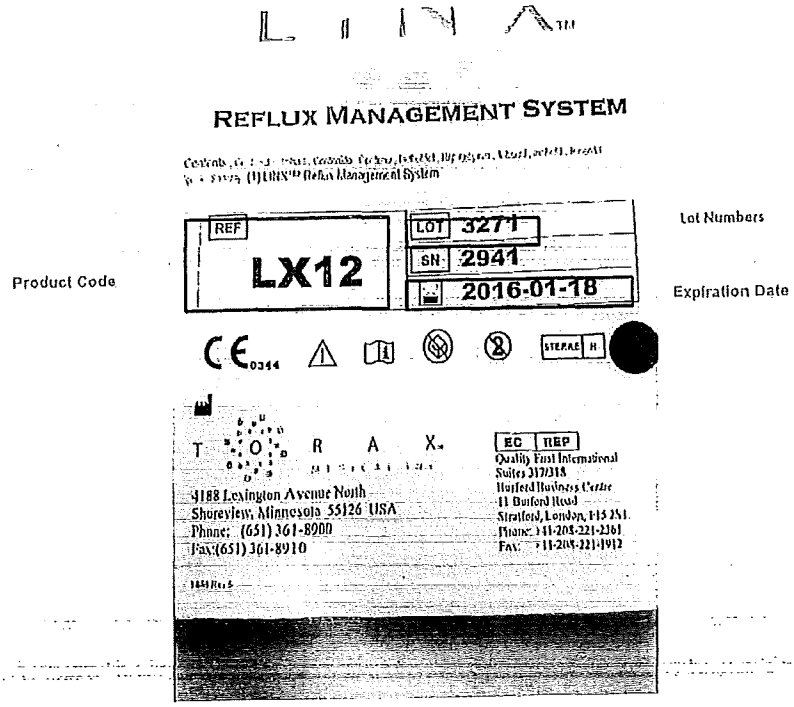
0.7T LINX® CARTON (Model Number LX-xx)



Product Code

Lot Numbers

Expiration Date

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[Account Name]
[Account Address]
[Customer Number]

ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and return this form to brf@toraxmedical.com **within 3 business days, even if you do not have the product subject to this recall to return.**

If you have product subject to this recall to return, please make a photocopy of your completed BRF and enclose with your return and ship the product and copy of the form to Torax Medical using the pre-paid FedEx shipping label provided. Thank you for your cooperation.

Product Inventory – Please check one:

☐ **We have NO remaining LINX Reflux Management System subject to this recall.**

☐ **We have LINX Reflux Management System subject to this recall and are returning the product listed below and requesting replacement product.**

PRODUCT NAME	PRODUCT CODE	LOT #	Quantity Returning (Eaches)
Print Name of Person Completing Form:		Telephone Number:	
Signed*:		Date:	
*Your signature provides confirmation that you have received and understood this notification			
LINX Reflux Management System			